

### **REMARKS**

Upon entry of this paper, claims 19-68 and 70-83 will be pending in the application. Claims 32-40, 48-57, 66-69, and 74-83 are elected and are presented for consideration. Claims 1-18 were previously canceled and claims 19-31, 41-47, 58-65, and 70-73 remain withdrawn from consideration. Applicant hereby amends claims 32, 40, 48, 57, 66, 68, and 74 and cancels claim 69. Applicant submits that these claim amendments introduce no new matter to the application. Support for the claim amendments can be found, e.g., at paragraphs [0002], [0025], [0041], [0048], [0055], [0117], [0174]-[0178], [0184], Figures 4, 6, 8, 9, 10, 12, of Applicant's Published Application (No. 2009-0014012), and in the claims as originally filed.

#### **Rejection Under 35 U.S.C. § 112**

The Office Action rejects claim 69 under 35 U.S.C. § 112, second paragraph, as being “indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as its invention.” (Office Action at pages 2-3.) Applicant hereby cancels claim 69 making this ground of rejection moot.

#### **Rejection Under 35 U.S.C. § 101**

The Office Action rejects claims 40 and 57 under 35 U.S.C. § 101 “because the claimed invention is directed to non-statutory subject matter.” (Office Action at page 3.) More specifically, the Office Action states that these claims appear “to claim the patient’s pharynx, the patient’s oral cavity, the patient’s tooth and the patient’s mouth, which are non-statutory subject matter.” (Id.) Without acquiescing to the rejection, Applicant hereby amends claims 40 and 57 so that it is clear that these tissue structures are not claimed. Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of these claims under 35 U.S.C. § 101.

The Office Action next rejects claims 66, 80, and 81 under 35 U.S.C. § 101 “because the claimed invention is directed to non-statutory subject matter.” (Id.) Claims 80 and 81 depend from claim 66. More specifically, the Office Action states that these claims appear “to claim the patient’s tongue, which is non-statutory subject matter.” (Id. at pages 3-4.) Without acquiescing to the rejection, Applicant hereby amends claim 66 so that it is clear that the tongue is not

claimed. Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of these claims under 35 U.S.C. § 101.

The Office Action next rejects claims 74 and 75 under 35 U.S.C. § 101 “because the claimed invention is directed to non-statutory subject matter.” (Office Action at page 4.) Claim 75 depends from claim 74. More specifically, the Office Action states that these claims appear “to claim the soft tissue, which is non-statutory subject matter.” (Id.) Without acquiescing to the rejection, Applicant hereby amends claim 74 so that it is clear that the soft tissue is not claimed. Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of these claims under 35 U.S.C. § 101.

**Rejection Under 35 U.S.C. § 102(e)**

The Office Action rejects claims 32-34, 40, 48-52, 55, 57, 66, 68, 69, 74, and 75 under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 5,961,440 to Schweich, Jr. et al. (“Schweich”). Of these, claims 32, 48, 66, 68, and 74 are independent.

Applicant respectfully submits that Schweich fails to disclose each and every element of independent claims 32, 48, 66, 68, and 74. Applicant amends each of these independent claims to recite a transmucosal insertion into a soft tissue. Applicant submits that Schweich does not anticipate these claims at least because Schweich fails to disclose a shaft configured for transmucosal insertion into the soft tissue. Schweich describes an “apparatus for treatment of a failing heart by reducing the wall tension therein.” (Schweich at Abstract.) The “apparatus includes a tension member for drawing at least two walls of the heart chamber toward each other to reduce the radius or area of the heart chamber in at least one cross sectional plane.” (Id. at Col. 2, Lines 56-59.) The tension members are “disposed at opposite ends for engagement with the heart or chamber wall.” (Id. at Col. 2, Lines 59-61.)

In contrast to an apparatus for reducing tension of a heart, Applicant’s amended independent claims 32, 48, 66, 68, and 74 recite a shaft configured for transmucosal insertion into the soft tissue. Embodiments of Applicant’s invention include a retractor member that “presses on the mucosal surface of the tongue, soft palate, pharyngeal walls, or supraglottic larynx.” (Applicant’s Publication Patent Application No. 2009/0014012 at ¶ [0184].) Mucosal

linings cover cavities that are exposed to the environment outside the body and include, e.g., the tongue, pharynx, and mouth.

Devices that pass through the mucosal lining and devices that do not pass through the mucosal lining (e.g., devices that are used for the heart, which is entirely enclosed in the body and not exposed to the external environment) require different considerations for the sizing, placement, and tensions of such devices. For example, it is well-known that a device configured for transmucosal insertion into soft tissue, such as Applicant's device, must allow for fluid drainage from the insertion (e.g., the internal area of the soft tissue that is in contact with the shaft) to prevent infection. (See e.g., Applicant's Publication Patent Application No. 2009/0014012 at ¶¶ [0162], [0183].) This is because the device connects the interior of the body to its exterior, specifically the mouth. The mouth is known to contain great amounts of pathogenic bacteria capable of causing serious life threatening infections. To prevent this, an ongoing seepage of fluid is needed from the internal shaft of the device toward its ends to wash bacteria out. Without this flow, fluid contaminated with bacteria will incubate and cause an infection along the shaft.

In contrast, one skilled in the art also knows that the device of Schweich, which has tension members disposed for engagement with the heart wall, must include a mechanism to prevent fluid leakage/scepage (e.g., blood) from the heart, where the device punctures the heart wall. Specifically, blood within the heart is always at a high pressure and literally squirts out of any puncture. Even minor punctures of the heart cause bleeding that can cause death in minutes. Moreover, high pressure blood will track along any smooth surface to escape. Generally the only approaches to preventing leaking blood in the heart require implantation into heart with growth of tissue into and around the implant. Accordingly, the leak prevention features mandatory in Schweich, if applied to a transmucosal insertion (as recited in Applicant's claims), would result in infection and thus would not be useable for this purpose. Schweich is not configured for transmucosal insertion.

In view of the foregoing, Applicant respectfully submits that Schweich fails to teach or suggest each and every element of independent claims 32, 48, 66, 68, and 74 at least because Schweich fails to disclose a shaft configured for transmucosal insertion into soft tissue. Therefore, Applicant respectfully requests that the Examiner reconsider and withdraw the

rejection of these claims under 35 U.S.C. § 102(e) in view of Schweich. Furthermore, Applicant respectfully submits that claims 33-34, 40, 49-52, 55, 57, 69, and 75 are also allowable as each depends from an allowable independent claim.

**Rejection Under 35 U.S.C. § 103(a)**

The Office Action rejects dependent claims 35, 37, 53, 56, 67, and 76-83 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Schweich. As discussed above, Schweich fails to teach or suggest each and every element of amended independent claims 32, 48, 66, 68, and 74. Applicant respectfully submits that claims 35, 37, 53, 56, 67, and 76-83 are allowable as each depends from an allowable independent claim.

The Office Action also rejects dependent claims 36, 38, 39, and 54 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Schweich in view of U.S. Patent No. 4,254,774 to Boretos ("Boretos"). As discussed above, Schweich fails to teach or suggest each and every element of independent claims 32, 48, 66, 68, and 74. Applicant submits that Boretos does not cure the defects of Schweich.

Boretos describes the manufacture of catheters with external diameters less than 1 mm and external balloons with walls less than 0.002 inches in thickness. Applicant submits that Boretos does not cure the deficiencies of Schweich in that Boretos, either alone or in combination with Schweich, as Boretos does not teach or suggest that a shaft configured for transmucosal insertion into a soft tissue. Applicant also respectfully submits that claims 36, 38, 39, and 54 are allowable as they depend from allowable independent claims.

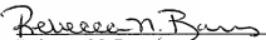
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**Conclusion**

Applicant requests that the Examiner reconsider the application and claims in light of the foregoing amendments and remarks, and respectfully submits that the claims are in condition for allowance. The Examiner is invited to call the undersigned at the number below to discuss the application.

Respectfully submitted,

Date: September 29, 2011  
Reg. No.: 62,751  
Tel. No.: (617) 526-9870  
Fax No.: (617) 526-9899

  
Rebecca N. Barnes  
Attorney for the Applicant(s)  
Proskauer Rose LLP  
One International Place  
Boston, MA 02110-2600